

**TECHNICAL REVIEW DOCUMENT**  
**for**  
**MODIFICATION TO OPERATING PERMIT 95OPBO150**

Corden Pharma Colorado, Inc.  
Boulder County  
Source ID 0130025

Prepared by Jacqueline Joyce  
May 2011

Revised August 26, 2011 to address Administrative Amendment received prior to revised permit issuance.

**I. Purpose:**

This document establishes the decisions made regarding the requested modification to the Operating Permit for Roche Colorado Corporation (RCC). This document provides information describing the type of modification and the changes made to the permit as requested by the source and the changes made due to the Division's analysis. This document is designed for reference during review of the proposed permit by EPA and for future reference by the Division to aid in any additional permit modifications at this facility. The conclusions made in this report are based on the information provided in the request for modification submitted to the Division on April 20, 2011, e-mail correspondence and telephone conversations with the source. Prior to issuance of the revised permit RCC indicated an upcoming complete share sale of Roche Colorado to Corden U.S., LLC which would result in a name change. RCC submitted an administrative amendment on August 22, 2011 to reflect the name change from RCC to Corden Pharma Colorado, Inc. The final revised permit reflects the name change. This narrative is intended only as an adjunct for the reviewer and has no legal standing.

Any revisions made to the underlying construction permits associated with this facility made in conjunction with the processing of this operating permit application have been reviewed in accordance with the requirements of Regulation No. 3, Part B, Construction Permits, and have been found to meet all applicable substantive and procedural requirements. This operating permit incorporates and shall be considered to be a combined construction/operating permit for any such revision, and the permittee shall be allowed to operate under the revised conditions upon issuance of this operating permit without applying for a revision to this permit or for an additional or revised construction permit.

**II. Description of Permit Modification Request/Modification Type**

The Operating Permit for Roche Colorado Corporation (RCC) was issued on June 1, 2000, renewed on April 1, 2007 and last revised on November 13, 2009.

RCC submitted a request to modify the permit on April 20, 2011. Under the alternate operating scenarios (AOS) in Section I, Condition 2.2.3 of the permit, RCC may begin commercial production with emissions in excess of de minimis levels in the areas that are currently exempt or insignificant sources (e.g. bench-scale laboratory equipment). RCC is planning to operate under the AOS in Section I, Condition 2.2.3 to produce Methyl Magnesium Bromide Grignard (MeMgBr Grignard) on bench-scale laboratory equipment. MeMgBr Grignard is currently purchased from an outside vendor. The production of MeMgBr Grignard requires the use of methyl bromide, which is a Class I, Group VI controlled substance under 40 CFR Part 82, Protection of Stratospheric Ozone. Since methyl bromide is a reactant in the proposed process and is transformed, use of the banned substance is allowed but is subject to recordkeeping and reporting requirements. Since the relevant recordkeeping and reporting requirements are not included in the permit, operating under the AOS in Section I, Condition 2.2.3 is not allowed. Therefore, RCC submitted a request on April 20, 2011 to incorporate the appropriate applicable requirements into the permit.

In the application, RCC indicated that emissions from the production of MeMgBr Grignard are 1 lb of VOC per batch (in this process all VOCs are HAPs), with a maximum expected production of 4 batches per year.

Colorado Regulation No. 3, Part C, Section X.A identifies those modifications that can be processed under the minor permit modification procedures. Specifically, minor permit modifications “are not otherwise required by the Division to be processed as a significant modification” (Colorado Regulation No. 3, Part C, Section X.A.6).

The Division requires that “any change that causes a significant increase in emissions” be processed as a significant modification (Colorado Regulation No. 3, Part C, Section I.A.7.(a)). According to Part G of Regulation No. 3 (Section I.L, revisions adopted July 15, 1993, Subsection I.G for modifications) the Division considers that a significant increase in emissions is an increase above the PSD significance. As previously indicated emissions from this project are well below the PSD significance level of 40 tons/yr of VOC.

This modification is not otherwise restricted from processing as a minor modification as it does not violate applicable requirements, change or require a case-by-case requirement, significantly modify existing monitoring, recordkeeping and reporting requirements and establish or change limits for which there is no underlying applicable requirement (see Colorado Regulation No. 3, Part C, Section X.A). In addition, this modification is not specifically required to be processed as a significant modification. Therefore, the Division considers that this modification qualifies as a minor modification.

### **III. Modeling**

The source is not requesting an increase in permitted emissions with this modification; therefore, modeling is not warranted. As previously indicated, the emissions associated with this modification are expected to be much less than the APEN de minimis level of 1 ton/yr of VOC.

#### **IV. Discussion of Modifications Made**

##### **Source Requested Modifications**

The Division addressed the source's requested modifications as follows:

##### **Section II.1**

- Based on comments submitted via e-mail on June 10, 2011, revisions were made to the description in Condition 1.1 to reflect updated operations at the facility.

##### **Section II.4**

- Added the relevant recordkeeping and reporting requirements from 40 CFR Part 82 as "new" Condition 4.8.

##### **Section II.14**

- Revised the table in Condition 14.5 to include the MeMGBr Grignard process.

##### **Other Modifications**

In addition to the requested modifications made by the source, the Division used this opportunity to include changes to make the permit more consistent with recently issued permits, include comments made by EPA on other Operating Permits, as well as correct errors or omissions identified during inspections and/or discrepancies identified during review of this modification.

The Division has made the following revisions, based on recent internal permit processing decisions and EPA comments on other permits, to the RCC Operating Permit with the source's requested modifications. These changes are as follows:

##### **Section I – General Activities and Summary**

- Changed the citation for the definition of 8-hour ozone control area in Condition 1.1.

##### **Section II.4 – Pharmaceutical and Non-Pharmaceutical Production**

- The summary table was revised to include Conditions 4.6 and 4.7.

#### Section II.6 – Raw Material Storage in Tank Farms

- The summary table was revised to include Condition 6.7.

#### Section III – Permit Shield

- Removed 40 CFR Part 82 Subpart A from the shield for non-applicable requirements (Section III.1), since these requirements now apply.

#### Section IV – General Conditions

- Updated the version date.
- Condition 29 (VOC) was revised primarily to add the provisions in Reg 7, Section III.C as paragraph e although other minor language and format changes were made.

#### Appendices

- Changed the Division contact for reports in Appendix D.